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| EXAMINER |
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BLANCO, JAVIER G

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| ART UNIT | PAPER NUMBER |
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3738

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05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,186

Applicant(s)

SUTTON ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) 11, 14, 17, 18, 20-23, 26-46 and 48-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13, 15, 16, 19, 24, 25, and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the Species embodied in independent claims 1 and 47 ("Species A"), **Implant:** Species A (embodied in Figure 1), **Locking Mechanism:** Species B (embodied in Figure 3), **Adjustment Mechanism:** Species A (embodied in Figure 14), and **Sensor:** Species D (Optical) in the reply filed on February 9, 2007 is acknowledged.
2. Claims 14, 17, 18, 20, 22, 23, 28-46, and 48-109 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 9, 2007.
3. It is noted that dependent claim 11 is drawn to either of non-elected Species B (embodied in Figure 2) or non-elected Species C (embodied in Figure 7). Also, it is noted that dependent claim 21 is drawn to non-elected Species C (embodied in Figure 7). Further (according to the Specification), the means comprising a motor (see claim 26) and means comprising a hydraulic means (see claim 27) is not disclosed as part of elected Species A (embodied in Figure 1). Therefore, claims 11, 21, 26, and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

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b. Therefore, the “an inner surface having a first articulation surface” (see claim 1 AND claim 47) must be shown or the feature(s) canceled from the claim(s). According to the Specification (see Figures 1A and 1B) articulation surface 24 is located on outer surface 23 (not inner surface 25, as claimed in claim 1). No new matter should be entered.

b. Therefore, the “measuring means” (see claim 24) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

c. Therefore, the “adapted to be actuated telemetrically” (see claim 25) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

d. Therefore, the “motor” (see claim 26) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

e. Therefore, the “hydraulic means” (see claim 27) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet”

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 9, 10, 13, 15, and 24 are objected to because of the following informalities:

a. Regarding each of claims 9 and 10, please substitute “means” with --means for capturing--.

Appropriate correction is required.

b. Regarding each of claims 13 and 15, please substitute “claim 5” with --claim 7 ~~5~~--. Otherwise said limitations will lack antecedent basis. Appropriate correction is required.

c. Regarding claim 24, please substitute “means is adapted” with --means is adapted--.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1-10, 12, 13, 15, 16, 19, 24, 25, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 1, the limitation “an inner surface having a first articulation surface” is indefinite as to the scope of the invention. According to the Specification (see Figures 1A and 1B) articulation surface 24 is located on outer surface 23 (not inner surface 25, as claimed in

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claim 1). Said subject matter will be interpreted "as best understood". Claims 2-10, 12, 13, 15, 16, 19, 24, and 25 depend on claim 1.

b. Regarding claim 2, "the elongated recess" (see line 3) lacks antecedent basis. Claims 3-10, 12, 13, 15, 16, and 19 depend on claim 2. Also, said limitation is indefinite as to the scope of the invention. Does it means the plate has an elongated channel AND an elongated recess? Said subject matter will be interpreted "as best understood".

c. Regarding claim 7, "the threaded throughhole" (see line 3) lacks antecedent basis.

d. Regarding claim 24, "the captured screw" (see line 3) lacks antecedent basis.

e. Regarding claim 47, the limitation "an inner surface having a first articulation surface" is indefinite as to the scope of the invention. According to the Specification (see Figures 1A and 1B) articulation surface 24 is located on outer surface 23 (not inner surface 25, as claimed in claim 47). Said subject matter will be interpreted "as best understood".

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-10, 12, 13, 15, 16, 19, 24, 25, and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12, 13, 15, 18-20, 23-26, 37, 39, 40, and 46-48 of copending Application No. 11/015,927.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a prosthetic endplate comprising an outer plate, an inner plate, and means for adjusting/moving one plate in relation to the other plate. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-10, 12, 13, 15, 16, 19, 24, 25, and 47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hochshuler et al. (US 6,045,579 A).

Referring to Figures 6A and 7-16, Hochshuler et al. disclose a method of adjusting a position of a prosthetic endplate, comprising the steps of:

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- a) Providing a prosthetic endplate having an anterior end (22) and a posterior end (24), the endplate comprising (i) an outer plate (14) comprising an outer surface, an inner surface (**first interpretation:** inner surface of plate 14; **second interpretation:** rib 85; **third interpretation:** inner surface of plate 14 + rib 85), and a body portion therebetween, and (ii) an inner plate (12) comprising an outer surface, an inner surface (**first interpretation:** inner surface of plate 12; **second interpretation:** rib 84; **third interpretation:** inner surface of plate 12 + rib 84), and a body portion therebetween,
- b) Fixing the outer surface of the outer plate to a first vertebral body to produce a first relative position of the inner plate upon the outer plate, and
- c) Selectively adjusting (i.e., “means for selectively adjusting”) the first relative position to a second relative position of the inner plate upon the outer plate.

The inner surfaces comprise an elongated channel/recess (Figures 6-9: slots 60; Figures 10-15: slot 90 and/or slot 92; Figure 16: slots 100, 104 and/or slots 102, 106) and an elongated projection (Figures 6-9: struts 30, which run in the anterior-posterior direction; Figures 10-15: pin 86 and/or pin 88; Figure 16: pin 86 and/or pin 88) *adapted to mate* with said elongated channel/recess. Said elongated channel/recess is formed upon the inner surface of the inner plate and said projection is formed upon the inner surface of the outer plate. Alternatively (as shown in the Figures), said elongated channel/recess is formed upon the inner surface of the outer plate and said projection is formed upon the inner surface of the inner plate (i.e., reversal of parts). The elongated projection comprises a through-hole (e.g., bore) running in the direction of the elongation (Figures 6-9: bore receiving pin 70; Figures 10-15: bores of pin 86 and/or pin 88; Figure 16: bores of pin 86 and/or pin 88), wherein the through-hole (e.g., bore) is threaded (see

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column 9, lines 23-26; column 10, lines 29-34) which thread is complementary to the thread of a screw (screw 80) being disposed within the through-hole (e.g., bore). The channel/recess comprises means for capturing the screw such as a shoulder, neck, or counterbore (see Figures 14 and 15), or a recess in the shaft of screw 80 adapted to receive a locking pin (Figures 14 and 15: locking ring/clip 98). The “locking means for locking the screw” (see claims 15 and 16) is the cam of cam pins 86, 88. It is inherent the use of “measuring means” (e.g., indicia, markings, visual, etc.) in order to access the position, degree of rotation, degree of motion, etc. of the plates.

12. Claims 1-5, 24, 25, and 47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Young et al. (US 6,190,414 B1).

Referring to Figures 7, 10, 13, and 14, Young et al. disclose a method of adjusting a position of a prosthetic endplate, comprising the steps of:

- a) Providing a prosthetic endplate having an anterior end and a posterior end, the endplate comprising (i) an outer plate (160) comprising an outer surface, an inner surface, and a body portion therebetween, and (ii) an inner plate (158) comprising an outer surface, an inner surface, and a body portion therebetween,
- b) Fixing the outer surface of the outer plate to a first vertebral body to produce a first relative position of the inner plate upon the outer plate, and
- c) Selectively adjusting (i.e., “means for selectively adjusting”) the first relative position to a second relative position of the inner plate upon the outer plate.

The inner surfaces comprise an elongated channel/recess (Figure 9: channel/recess at one end of plate 158; Figures 13 and 14: channel/recess formed by component 142) and an elongated projection (Figure 9: cylindrical projection at one end of plate 160; Figures 13 and 14: projection 140) *adapted to mate* with said elongated channel/recess. Said elongated channel/recess is formed upon the inner surface of the inner plate and said projection is formed upon the inner surface of the outer plate. Alternatively (as shown in the Figures), said elongated channel/recess is formed upon the inner surface of the outer plate and said projection is formed upon the inner surface of the inner plate (i.e., reversal of parts). The elongated projection comprises a through-hole (e.g., bore) running in the direction of the elongation. It is inherent the use of “measuring means” (e.g., indicia, markings, visual, etc.) in order to access the position, degree of rotation, degree of motion, etc. of the plates.

13. Claims 1-10, 13, 15, 16, 19, 24, 25, and 47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cohen et al. (US 6,454,806 B1).

Referring to Figures 14A-14C and 15A-15C, Cohen et al. disclose a method of adjusting a position of a prosthetic endplate, comprising the steps of:

a) Providing a prosthetic endplate having an anterior end and a posterior end, the endplate comprising (i) an outer plate (Figures 14A-14C: plate 91; Figures 15A-15C: plate 110) comprising an outer surface, an inner surface, and a body portion therebetween, and (ii) an inner plate (Figures 14A-14C: plate 91; Figures 15A-15C: plate 110) comprising an outer surface, an inner surface, and a body portion therebetween,

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- b) Fixing the outer surface of the outer plate to a first vertebral body to produce a first relative position of the inner plate upon the outer plate, and
- c) Selectively adjusting (i.e., “means for selectively adjusting”) the first relative position to a second relative position of the inner plate upon the outer plate.

The inner surfaces comprise an elongated channel/recess (Figures 14A-14C: groove 94 and/or inner channel 95; Figures 15A-15C: grooves 115) and an elongated projection (Figures 14A-14C: wedges 92; Figures 15A-15C: guides 114) *adapted to mate* with said elongated channel/recess, wherein the elongated projection runs in the anterior-posterior direction. Said elongated channel/recess is formed upon the inner surface of the inner plate and said projection is formed upon the inner surface of the outer plate. Alternatively (as shown in the Figures), said elongated channel/recess is formed upon the inner surface of the outer plate and said projection is formed upon the inner surface of the inner plate (i.e., reversal of parts). The elongated projection comprises a through-hole (e.g., bore) running in the direction of the elongation (see Figures 14A-14C), wherein the through-hole (e.g., bore) is threaded (see Figures 14A-14C; see column 10, lines 28-41) which thread is complementary to the thread of a screw (screw 93) being disposed within the through-hole (e.g., bore). The channel/recess comprises means for capturing the screw such as a shoulder or neck (e.g., counterbore). Cohen et al. disclose “locking means for locking the screw” (see claims 15 and 16) as cam 112 (see Figures 15A-15C). It is inherent the use of “measuring means” (e.g., indicia, markings, visual, etc.) in order to access the position, degree of rotation, degree of motion, etc. of the plates.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

April 28, 2007



David H. Willse
Primary Examiner